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By CM/ECF

December 5, 2022

Honorable Lorna G. Schofield
U.S. District Court
Southern District of New York
500 Pearl Street
New York, NY 10007

Re: *Portal Instruments, Inc. v. LEO Pharma A/S*, 1:22-cv-09156-LGS (S.D.N.Y.)

Dear Judge Schofield:

We represent Defendant LEO Pharma A/S (“LEO”) and respectfully submit this pre-motion letter, pursuant to Rule III.C.2 of Your Honor’s Individual Rules, in anticipation of LEO’s motion to dismiss the Complaint filed by Portal Instruments, Inc. (“Portal”).

I. Background

This case concerns a Collaboration and License Agreement (the “Agreement”) between LEO and Portal, under which the parties agreed to jointly develop a needle-free drug delivery device to be used with LEO’s drug products. The Agreement permitted LEO to elect whether to develop a system capable of delivering a dose of LEO’s drug products in a single injection, a system capable of delivering a dose in two injections, or both systems. Compl. ¶ 11-12; Agreement (Exhibit A to the unredacted Complaint filed under seal (“Ex. A”)) § 4.2. Following any such election, LEO was required to make certain installment payments towards a Development Fee for a specified number of quarters or until it elected, in its sole discretion, to cease development. Agreement § 7.2(a). In the event of an election to cease development, the Agreement provides that “LEO Pharma shall have no obligation to make any future installment payments towards the ... Development Fee.” *Id.* The Agreement separately provides for certain milestone payments, which are to be paid only upon satisfaction of certain development milestones defined in the Agreement. *Id.* § 7.3.

In January 2020, LEO elected to develop the single-injection system, and began making installment payments to Portal. Compl. ¶¶ 17-18. On September 15, 2021, LEO formally notified Portal that it was (1) electing to cease development with “immediate effect,” and (2) terminating the Agreement effective December 22, 2021. Compl. ¶¶ 20-21; Termination Notice (Ex. B). LEO ceased making installment payments following its election to cease development, in keeping with the contract provision stating that if “LEO Pharma elects to cease the Development of the [single-injection system], then *LEO Pharma shall have no obligation to*

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make any future installment payments towards the [single-injection system] Development Fee.” Agreement § 7.2(a) (emphasis added).

In response to LEO’s election and termination, Portal filed this action asserting three claims against LEO. First, Portal asserts that LEO breached the Agreement by not paying Portal an installment payment that Portal claims was payable two weeks following LEO’s election to cease development. *See* Compl. ¶¶ 62-67. Second, Portal asserts that LEO breached the Agreement by not providing Portal a Milestone Payment allegedly due after the completion of a study determining that a bioequivalence criteria has been met. *See id.* ¶¶ 68-73. Third, Portal asserts that LEO breached the implied covenant of good faith and fair dealing by not paying the Development Fee and Milestone Payment. *See id.* ¶¶ 74-82. As explained below, all three claims fail to state a claim for relief.

II. Portal’s Complaint Fails to State a Claim for Relief.

1. The Development Fee Claim. The Development Fee claim fails because Portal’s own allegations and the Agreement attached to the Complaint demonstrate that LEO had no obligation to pay this fee after it elected to cease development of the single-injection system. As the Complaint admits, the Agreement provides LEO the right to, at “any point after making its election [of which system to develop], in its sole discretion, provide Portal with written notification to ... cease ...[development].” Compl. ¶ 12 (quoting Agreement § 4.2). The Agreement further provides that if “LEO Pharma elects to cease the Development of the [system], then *LEO Pharma shall have no obligation to make any future installment payments* towards the [single-injection system] Development Fee.” Agreement § 7.2(a) (emphasis added).

Portal admits that on September 15, 2021, LEO elected to cease development, “with immediate effect.” Compl. ¶ 21; *see also* Termination Notice. As LEO informed Portal at the time, LEO’s election to cease development meant that, under Section 7.2(a) of the Agreement, it had no obligation to make any future Development Fee payments, including the Eighth Development Fee payment, which would have become due two weeks after LEO’s election to cease development. Compl. ¶¶ 21, 28-29; Termination Notice.

Portal’s Complaint argues that LEO should be required to make the Eighth Development Fee payment because LEO’s *termination* of the Agreement was not effective until after that fee was due, but that confuses LEO’s right to *terminate* the Agreement with the right of LEO to *elect to cease development* of a device and cartridge system. The right to terminate under Section 17.2 and the right to cease development under Sections 4.2 and 7.2 are distinct and provided for separately under the Agreement. Moreover, Portal’s argument is contrary to the plain language of the Agreement making clear that LEO had “no obligation to make any future [Development Fee] installment payments” after electing to cease development. Agreement § 7.2(a).

In light of the clear contract language, Portal fails to state a claim for breach of the Development Fee provisions of the Agreement.

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2. The Milestone Payment Claim. Portal’s Milestone Payment claim should also be dismissed because the Complaint does not allege facts demonstrating that the payment was due. Under the Agreement, the Milestone Payment is due after the “[c]ompletion of a pharmacokinetic study in animals in which a Third Party determines that delivery of LEO Pharma’s Drug via the Device is bioequivalent to delivery via a needle/syringe ... which *shall include a statement that the bioequivalence criteria have been met*” Agreement § 7.3 (emphasis added). Express conditions such as this one “must be literally performed; substantial performance will not suffice.” *In re Johns-Manville Corp.*, 759 F.3d 206, 214 (2d Cir. 2014) (quoting *HR Cap. Partners LP v. Presstek, Inc.*, 12 N.Y.3d 640, 645 (2009)).

The Complaint, however, does not allege the completion of any study including “a statement that the bioequivalence criteria have been met.” Instead, the Complaint points only to a study that allegedly made “a *surrogate finding* of bioequivalence.” Compl. ¶ 50 (emphasis added). Nor does the study report itself—which is quoted in, and thus incorporated by reference in, the Complaint—include “a statement that bioequivalence criteria have been met.” Indeed, the report does not even mention the word “bioequivalence.”

Because Portal’s own allegations, and documents incorporated in the Complaint by reference, demonstrate that the obligation to make the Milestone Payment was not triggered, Portal’s Complaint fails to state a claim for breach of the Milestone provision of the contract.

3. The Good Faith and Fair Dealing Claim. Finally, Portal’s claim for breach of the implied covenant of good faith and fair dealing fails to state a claim because it is duplicative of its breach of contract claims. “New York law ... does not recognize a separate cause of action for breach of the implied covenant of good faith and fair dealing when,” as here, “a breach of contract claim, based upon the same facts, is also pled.” *Harris v. Provident Life & Acc. Ins. Co.*, 310 F.3d 73, 81 (2d Cir. 2002). Nor can the implied covenant be used to vary the express terms of a written agreement, as Portal seeks to do here by invoking the implied covenant in an effort to (i) circumvent LEO’s clear contractual right to cease paying Development Fee installments following an election to cease development, and (ii) avoid an express contractual condition to LEO’s milestone payment obligations. *See In Touch Concepts, Inc. v. Celco P’ship*, 788 F.3d 98, 102 (2d Cir. 2015).

III. Proposed Briefing Schedule for LEO’s Motion to Dismiss.

LEO respectfully requests that the Court enter the following briefing schedule for its motion to dismiss: LEO’s motion due January 15, 2023; Portal’s opposition February 27, 2023; and LEO’s reply March 13, 2023. We thank the Court for its attention to this matter.

Respectfully submitted,

/s/ Mark P. Gimbel

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